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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,135	04/06/2007	David Spriggs	MSK.P-071	3258
57381	7590	12/09/2009	EXAMINER	
Larson & Anderson, LLC			SANG, HONG	
P.O. BOX 4928			ART UNIT	
DILLON, CO 80435			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,135	Applicant(s) SPRIGGS ET AL.	
	Examiner HONG SANG	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Spriggs et al.

1. Applicant's response filed on 9/8/2009 is acknowledged. Claims 1-14 are pending. Claims 15 and 16 have been cancelled. No claims have been amended.
2. Claims 1-14 are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 102

3. The rejection of claims 1, 2, 9 and 11-14 under 35 U.S.C. 102(b) as being anticipated by WO 00/19206 (Pub. Date: 4/6/2000, IDS) is maintained.

The response states that the instant claims are directed to ovarian cancer specifically, and the cited reference is not specific to any cancer. The response states that among the two patients who ultimately developed ovarian cancer, one of these two patients had an elevated YKL-40 level and the other did not. One patient having 196 µg/L is not statistically significant because it is not a "level greater than 95% of the median level" (i.e. 207 µg/L). Furthermore, there is no teaching that there was early stage ovarian cancer present in either the women who presented with ovarian cancer at some undisclosed time in the next five years.

Applicant's arguments have been carefully considered but are not persuasive. WO 00/19206 expressly teaches that their method of screening a cancer, detecting a cancer and/or evaluating the prognosis of a cancer in a mammal can be used for ovarian cancer (see page 3, line 4 and claim 41, for example). WO 00/19206 discloses

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that serum YKL-40 can identify patients with cancer before clinical symptoms appear, and therefore before the cancer would normally be discovered (see page to, lines 4-5). WO 00/19206 discloses that both patients who ultimately developed ovarian cancer had elevated YKL-40 level, 196 $\mu\text{g/L}$ and 298 $\mu\text{g/L}$, respectively (both are higher than the median level 99 $\mu\text{g/L}$). Although 196 $\mu\text{g/L}$ does not meet the level that is at least 95% of the median level (i.e. 207 $\mu\text{g/L}$), the level that is at least 95% of median level is merely a preferred cutoff point. WO 00/19206 teaches that in a particularly preferred embodiment, the assay is deemed to show a positive result when the difference between the sample and the “control” is statistically significant (e.g. at the 85% or greater, preferably at the 90% or greater, more preferably at the 95% or greater and most preferably at the 98% or greater confidence level) (see page 28, lines 25-28). A patient having a level of 196 $\mu\text{g/L}$ developed ovarian cancer clearly suggests that a lower cutoff point can be used for identifying ovarian cancer. For these reasons, the rejection is deemed proper and is therefore maintained.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over WO 00/19206 (Pub. Date: 4/6/2000, IDS), in view of Marton et al. (US 2003/0175832A1, Pub. Date 9/18/2003, effective filing date 11/16/2001), and Xu et al. (US 5,486,456, Date of Patent 1/23/1996) is maintained.

Applicant's presented same arguments as in 102 rejection and these arguments are not persuasive for the reasons set forth above.

Conclusion

5. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643

/Christopher H Yaen/
Primary Examiner, Art Unit 1643